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Guidance for the Reregistration of Pesticide Products Containing Dichlobenil as the Active Ingredient

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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of data requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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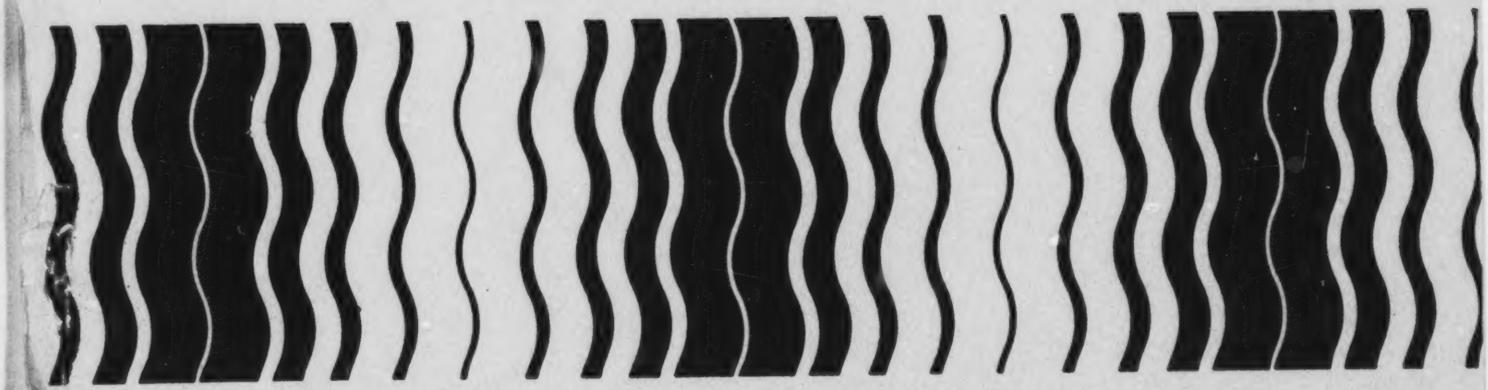

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

DICHLOBENIL

AS THE ACTIVE INGREDIENT

OPP NUMBER 027401

CAS NUMBER 1194-65-6

MAR 23 1987

ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF PESTICIDE PROGRAMS
WASHINGTON, D.C. 20460

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI: Acceptable Daily Intake

a.i.: Active ingredient

CAS: Chemical Abstract Society (number)

Core Classifications: A general guide to the acceptability of data for the purpose of supporting registration (invalid, supplementary, minimum, or guideline).

CSF: Confidential Statement of Formula

DNA: deoxyribonucleic acid

EPA: The Environmental Protection Agency, also "the Agency"

F_1, F_2: Refers to the generations in a multi-generation study

FIFRA: The Federal Insecticide, Fungicide, and Rodenticide Act

LC_{50}: (median lethal concentration) a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals, expressed as weight or volume of test substance per volume of air or water or per weight of feed (e.g., mg/l or ppm).

LD_{50}: (median lethal dose) a statistically derived single dose that can be expected to cause death in 50% of animals when administered by the route indicated, expressed as weight of substance per unit weight of test animal (e.g., mg/kg).

LEL: Lowest Effect Level

MPI: Maximum Permissible Intake

MRID: Master Record Indentification (number) - EPA's system of tracking studies used in support of registrations.

NPDES: National Pollution Discharge Elimination System

NOEL: No Observed Effect Level

OPP: The Office of Pesticide Programs

OES: Office of Endangered Species, U.S. Fish and Wildlife Service

PADI: Provisional Acceptable Daily Intake

PAI: Pure active ingredient

RACs: Raw Agricultural Commodities

Technical: Active ingredient as manufactured

TMRC: Theoretical Maximum Residue Contribution

I. INTRODUCTION

The Registration Standards Program

EPA has established the Registration Standards Program to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this standard. Pesticides have been grouped into use clusters and will be reviewed on the basis of a ranking scheme giving higher priority to: (1) pesticides in clusters used on food and feed crops; and (2) pesticides produced in large volumes.

The Registration Standards Program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide's active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. (See Section IV - Regulatory Position and Rationale). Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration.

2. Modification of product labels.

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants.

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals.

5. Modification of uses or formulation types.

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. DESCRIPTION OF CHEMICAL

The following chemical is covered by this Registration Standard:

Common name: Dichlobenil

Chemical name: 2,6-dichlorobenzonitrile

CAS number: 1194-65-6

Office of Pesticide Program Shaughnessy number: 027401

Empirical formula: $C_7H_3Cl_2N$

Trade names: Casoron®, H-133, Decabane®, 2,6-DBN, Code 133®

Year of Initial Registration: 1964

Chemical Family: Benzonitrile

Description of physical characteristics of chemical: White crystalline solid with a melting point of 145 to 146 °C. At 20 °C this chemical is soluble at 25 ppm in water, 10 g/100 g in methylene chloride and 4 g/100 g in Toluene.

B. USE PROFILE

Type of Pesticide: Herbicide

Pests Controlled: Broadleaf weeds and grasses (annual and perennial), and aquatic weeds.

Registered Uses: Terrestrial food and nonfood crop, aquatic nonfood, forestry, and commercial and industrial uses.

Predominant Use(s): Alfalfa and ladino clover crops, berry crops, grapes, pome fruits, stone fruits, citrus fruits, nuts, ornamental trees and shrubs, rights-of-way, industrial sites, and aquatic sites.

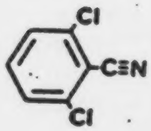
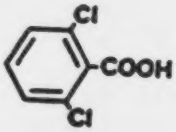
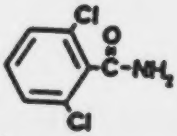
Mode of Activity: Dichlobenil stimulates oxygen utilization while inhibiting esterification of phosphorous, which results in reduced meristematic cell growth and inhibition of germination.

Formulation Types Registered: 99.5-96% Technical grade active ingredient (ai), 85.5%-85% formulation intermediate (FI), 2%, 4%, and 10% active ingredient (ai) granule (G); 50% ai wettable powder (WP); 1.73%, 1.77%, 2.1%, and 3.12% ai soluble concentrate/liquid (SC/L); and 6.75% ai liquid ready to use (RTU).

Method(s) of Application: Ground or aerial application.

Application Rates: Alfalfa and ladino clover 1.4 to 2.0 lb ai/A; 4 to 6 lb ai/A in cranberry bogs, granular mix 3.4 to 6.75 lb ai/A and up to 10 lb ai/A on very weedy bogs; 4 to 6 lb ai/A for control of annual weeds in bearing, nonbearing, nursery stock, noncitrus, nut crops; 4 to 7 lb ai/A in citrus nurseries; terrestrial nonfood crops 10 to 20 lb ai/A; aquatic weed control 7 to 15 lb. ai/A.

C. Chemical Structures

STUCTURE	CHEMICAL NAME	COMMON NAME OR ABBREVIATION
1/ 	2,6-dichlorobenzonitrile	dichlobenil
2/ 	2,6-dichlorobenzoic acid	2,6-DCBA
3/ 	2,6-dichlorobenzamide	BAM

1/ Chemical structure for the herbicide Dichlobenil.

2/ Chemical structure for the metabolite 2,6-dichlorobenzoic acid (2,6-DCBA).

3/ Chemical structure for the metabolite 2,6-dichlorobenzamide (BAM). [BAM is a primary metabolite of Dichlobenil produced by soil microbes (95%)].

III. AGENCY ASSESSMENT

A. SUMMARY

Dichlobenil has a low acute oral toxicity (Category III) and a moderate acute dermal toxicity (Category II). Acute inhalation, dermal sensitization, primary eye irritation, primary dermal irritation, reproduction studies, and a teratology study in a second species are required. Sufficient data have been submitted to satisfy the data requirement for a teratology study in rats. The oncogenic potential of dichlobenil could not be adequately determined from the study submitted. Oncogenicity studies are required in mice and rats. An animal metabolism study is also required. Dichlobenil is negative in a battery of mutagenicity tests for gene mutation, chromosomal aberration, deoxyribonucleic acid (DNA) repair, and transformation. No additional mutagenicity tests are required.

Available data are insufficient to fully assess the environmental fate and transformation of dichlobenil. Hydrolysis, photodegradation, metabolism, mobility, dissipation, and accumulation studies must be submitted.

The current data base suggests one major ecological problem, the aquatic use of dichlobenil. The guideline requirements for acute testing of dichlobenil are only partially satisfied.

The Agency is concerned about the potential for ground water contamination by dichlobenil. The Agency has determined that additional data are needed to characterize the potential for dichlobenil to enter ground water.

Data are available regarding residues of dichlobenil and its metabolite, 2,6-dichlorobenzoic acid (2,6-DCBA) in or on some plant commodities. Data are still required for the parent and 2,6-DCBA in or on several additonal commodities. Additional data are also required reflecting residues of the metabolite, 2,6-dichlorobenzamide (BAM) on all commodities.

B. PRELIMINARY RISK ASSESSMENT

Toxicology Characteristics

Acute Toxicity and Irritation Studies

Acute oral toxicity data place technical dichlobenil in Toxicity Category III (CAUTION). The acute dermal toxicity study indicates that technical dichlobenil is acutely lethal by the dermal route, placing it in Toxicity Category II (WARNING). Acute inhalation, primary eye irritation, primary dermal irritation and dermal sensitization studies have not been submitted and are required.

Subchronic Toxicity Studies

Sufficient data have been submitted to satisfy the data requirements for subchronic oral toxicity studies in a rodent species. Rats (12/sex/dose) were treated with dichlobenil in the diet for 13 weeks at doses of 0, 100, 1000, 3000, and 10,000 ppm (six males only). Compound-related effects included increased absolute and relative liver and kidney weights at 1000 ppm and above, hepatic degeneration and an absolute neutropenia and leukopenia at 3000 ppm and above, and mortality (five out of six) and hepatic necrosis at 10,000 ppm. The No-Observed-Effect-Level (NOEL) was 100 ppm (50 mg/kg/day) and the Lowest Effect Level (LEL) was 1000 ppm (500 mg/kg/day) based on increased absolute and relative liver and kidney weights.

The data requirements for a subchronic oral toxicity study in a nonrodent species have been satisfied by the chronic (2-year) dog feeding study.

Chronic Toxicity and Oncogenicity Studies

Data requirements for a chronic dog feeding study have been satisfied. Beagle dogs (4/sex/dose) were treated with dichlobenil in the diet for 24 months at doses of 0, 20, 50, and 350 ppm. The NOEL was 50 ppm (1.25 mg/kg/day) and the LEL was 350 ppm (8.75 mg/kg/day) based on 1) increased absolute and relative liver and thyroid weight in both sexes, 2) leukocytic infiltration and fibrinoid degeneration around the central hepatic veins in both sexes, 3) increases in serum alanine aminotransferase (SGPT) (females) and serum alkaline phosphatase (SAP) (males and females), and 4) increase in liver enzyme glucose-6-phosphatase (G6Pase) and glucose-6-phosphatase dehydrogenase (G6PD) activity (males and females).

In a core-supplementary two-year feeding/oncogenicity study, 50 male and 50 female Fisher 344 rats were treated with 0, 50, 400, or 3200 ppm of dichlobenil in the diet. A tentative NOEL has been set at 50 ppm (avg. 3.17 mg/kg/day) and a tentative LEL set at 400 ppm (avg. 27.8 mg/kg/day) based on the following lesions: suppression of body weight increase, depressed food consumption and liver and kidney effects characterized by elevated relative organ weights, clinical chemistry changes and non-neoplastic histopathologic changes. This 2-year rat feeding/oncogenicity study must be resubmitted and reevaluated, because of deficiencies in reporting the results, namely lack of adequate summary tables of survival, histopathological examinations and in-life observations.

The requirement for a new rat feeding/oncogenicity study will be reserved pending reevaluation of this study. A lifetime feeding study is required in the mouse in order to evaluate the oncogenic potential in mice.

Teratology

The data requirement for a teratology study in rats has been satisfied. Groups of 25 Wistar rats were treated by gavage on days 6 through 15 of gestation with 0, 20, 60, or 180 mg/kg/day of dichlobenil. The maternally toxic NOEL is 20 mg/kg/day and the LEL, based on decreased maternal weight gain, feed consumption, and feed efficiency is 60 mg/kg/day. The developmental NOEL is 60 mg/kg/day and the LEL is 180 mg/kg/day based on a slight increase in supernumary thoracic ribs.

A teratology study in a second species (non-rodent) is required.

Reproduction

The available rat reproduction study does not adequately evaluate the reproductive potential of dichlobenil because fewer than 10 litters were obtained per group per mating, only kidneys and livers were examined in the F2 generations, and the data were presented only in summary form. Wistar rats were treated with 0, 20, 50, or 100 ppm of dichlobenil in the diet. The systemic NOEL observed in the study was 20 ppm (1 mg/kg/day) and the LEL, based on body weight depression, was 50 ppm (2.5 mg/kg/day). The reproductive NOEL was 50 ppm and the LEL, based on decreased viability of F1a pups and decreased fertility for F2a and F2b parents, was 100 ppm. A new reproductive study is required.

Mutagenicity

Acceptable studies have been submitted to satisfy the data requirements for gene mutation, chromosomal aberration, and direct DNA damage. Dichlobenil showed no apparent mutagenic potential in bacteria with or without activation when tested _in vitro_ in mouse lymphoma. Dichlobenil was negative for chromosomal aberration when tested in the metaphase analysis assay using human lymphocytes. No direct (DNA) damage was apparent with dichlobenil in human HeLa epithelioid cells for DNA repair. There was no apparent transforming potential with activation in the BALB/3T3 transformation assay. No additional data are required.

Metabolism

There are currently no acceptable metabolism studies with dichlobenil. Several metabolism studies are required (plant, animal, soil and aquatic).

The manufacturing impurity (BAM) is the primary metabolite of dichlobenil produced microbiologically in the soil accounting for as much as 95% of all metabolites. Although BAM does not appear to be more acutely toxic than dichlobenil, there is a potential toxicity concern. Subchronic ingestion of BAM produces a neuromuscular effect in rats, not observed with the parent compound.

The metabolic pathways in plants for the degradation of dichlobenil and the nature of the residue of dichlobenil in ruminants and poultry have not been adequately elucidated, therefore, additional data are required. Although rat and rabbit studies of dichlobenil metabolism revealed no detectable residues of BAM or its hydroxy derivatives, plant and soil metabolism studies have provided evidence that a substantial portion of the terminal dichlobenil residues to which livestock may be exposed in feed commodities from treated crops may consist of BAM. On receipt of the data requested, the need for and nature of tolerances for residues in animal products will be determined. If residue studies reveal detectable levels of BAM in feed commodities or other metabolites of concern identified in the requested plant and animal metabolism studies, then livestock feeding studies using dichlobenil plus BAM (and other metabolites of concern) may be required.

Miscellaneous Subchronic toxicity for the metabolite BAM

A core-minimum subchronic oral rat study was submitted. Rats (10/sex/dose) were treated with BAM in the diet for 13 weeks at doses of 0, 50, 180, 600, and 2300 ppm. The NOEL (180 ppm [14 mg/kg/day]) and the LEL (600 ppm [49 mg/kg/day]) were based on decreased body weight gain and food efficiency, increased blood urea nitrogen (BUN), and reduced coagulation times. There was also a possible reduction in muscle tone.

C. OTHER SCIENCE FINDINGS

Environmental Characteristics

Available data are insufficient to fully assess the environmental fate and transformation of dichlobenil. Hydrolysis, photodegradation, metabolism, mobility, dissipation, and accumulation studies must be submitted.

Reentry data are not required because dichlobenil does not meet the toxicity or exposure criteria of 40 CFR 158.140. Dichlobenil does not meet the toxicity criteria of 40 CFR

158.140 since 1) the acute dermal toxicity of the technical grade of active ingredient is greater than 200 mg/kg (body weight); 2) the acute oral toxicity of the technical grade of active ingredient is greater than 50 mg/kg (body weight); and 3) no other adverse effects have been observed.

The exposure criteria are based on the pesticide's use patterns. The criteria for requirement of a proposed reentry interval and the supporting data are listed in 40 CFR §158.140 and are discussed in §130-3 of Subdivision K. These use patterns are characterized by a high likelihood of dermal or inhalation exposure to persons who reenter treated sites included in these classes which is not the case for dichlobenil.

The Agency is concerned about pesticide residues reaching ground water. Dichlobenil has the potential to reach ground water resources based on its chemical structure, water solubility and use patterns. The Agency has determined that additional data are needed to fully characterize the potential for dichlobenil to reach ground water.

Ecological Characteristics

Based on the available data, the aquatic use of dichlobenil presents the only major ecological concern. Dichlobenil is slightly toxic to game birds and moderately toxic to fish. Endangered species triggers have been exceeded based on toxicity and estimated exposure data. Available data are discussed as follows:

Toxicity to Fish and Aquatic Invertebrates

There are sufficient data to characterize the acute toxicity of dichlobenil as being of moderate toxicity to coldwater and warmwater fish.

A 50% Wettable Powder (WP) tested against five species of aquatic invertebrates suggests that the 50% WP is moderately to slightly toxic to aquatic invertebrates.

Two fish studies demonstrate the principle metabolite (2,6-DCBA) to be practically non-toxic to fish.

Direct application of a pesticide to water can present a potential risk to fish and aquatic invertebrates. Dichlobenil as both a 4% and 10% granular is registered to control aquatic weeds in lakes, ponds, and reservoirs. Present label directions permit treating of a third of the weed area. If a 6-acre feet pond was only treated (at a 15 lb. ai/A rate) for a third of its surface then the maximum estimated residues would be 0.25 ppm. This value is below the restricted use trigger; but still raises endangered species concerns for aquatic invertebrates.

Based upon the above calculations we are not restricting this pesticide at this time. Because there are concerns about persistence, accumulation, and groundwater contamination, we are requiring registrants to submit environmental fate studies including dissipation and accumulation studies in order to adequately address these concerns.

Toxicity to Birds

There is only partial information on avian acute toxicity However, with an LC_{50} = 1500 ppm, dichlobenil is slightly toxic to pheasants.

Endangered Species

There are sufficient data on avian and aquatic organisms to evaluate the hazard to endangered avian and aquatic species. Only the aquatic herbicide use may result in a potential hazard to aquatic invertebrates.

Alfalfa and ladino clover use directions specify aerial application. These uses compared to other terrestrial sites present even less hazard to aquatic organisms because 1) only granular products are registered for these crops thereby reducing drift, 2) use is limited (crops grown for seed in the Northwest), and 3) application rates are 1.4 to 2.0 lb ai/A.

Birds could be exposed to granules by consuming them as grit. The lowest LD_{50} is 1189 mg/kg to pheasants. With the LD_{50} of dichlobenil being approximately 1200 mg/kg to pheasants which is by an order of magnitude (10) greater than the level normally causing concern for bird deaths (100 mg/kg or less), there should be no problems for nonendangered or endangered bird species.

The Endangered Species Cluster Program is designed to assess the individual risk to endangered species from each of the chemicals registered for a given use pattern. The Agency is currently developing the clusters for endangered species (plant and animal) on aquatic and noncrop sites. The Office of Endangered Species (OES) will be requested to provide an opinion for dichlobenil along with other chemicals in those clusters.

Product Chemistry

The Agency has evaluated the available data which identify the composition, beginning materials, and manufacturing process and discuss the physical and chemical properties of dichlobenil. The Agency is concerned about the possibility of dichlobenil becoming contaminated with halogenated dibenzo-p-dioxins, dibenzofurans, and nitrosamines during manufacture.

The Agency's concern about dichlobenil is based upon its chemical structure (polyhalogenated cyclic compound). Available information suggests that halogenated dibenzo-p-dioxin and dibenzofuran contaminants may be formed during manufacture under certain conditions of temperature, pressure and alkalinity.

Registrants are required to analyze their products for nitrosamine contamination. The Agency is requesting data describing the maufacturing process for dichlobenil, with particular emphasis on data relating to the formation of dibenzo-p-dioxins or dibenzofurans. The manufacturing process description must describe each step of the manufacturing process, including specification of acceptable conditions of temperature, pressure or alkalinity. The Agency is particularly interested in the presence of elevated temperature, pressure or alkalinity at any stage of manufacture. If the active ingredient is manufactured at more than one facility, a description of the process used in each facility must be submitted. The discussion of the formation of impurities must pay particular attention to the possible formation of nitrosamines or halogenated dibenzo-p-dioxins or dibenzofurans.

D. TOLERANCE REASSESSMENT

Tolerances have been established for residues of dichlobenil in a variety of raw agricultural commodities (RACs), meat, fat, and meat byproducts (40 CFR 180.231). EPA has evaluated the residue and toxicology data supporting tolerances and has made the following regulatory determinations:

- Whether the current tolerances and food additive regulations are sufficient to cover the actual residues resulting from use (including uses registered under FIFRA section 24(c) and intrastate uses).
- Whether group tolerances can be established in accordance with 40 CFR 180.34(f).
- Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.
- Whether the tolerances are expressed accurately and in current terminology.

The regulatory results of the Agency's review are set out in Section IV.A., Regulatory Positions and Rationales.

1. Residue Data.

The residue data reviewed in support of these tolerances include the following:

a. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of dichlobenil. The established tolerances are based on occurrence of dichlobenil and its metabolite 2,6-DCBA. The manufacturing impurity BAM also occurs as a soil microbial metabolite of dichlobenil and may be present at significant levels in the soil following treatment. BAM will be added to the tolerance expression which already includes dichlobenil and the metabolite 2,6-DCBA.

b. Radiolabeled studies on the uptake, translocation, and metabolism of dichlobenil in plants which show that 2,6-DCBA is absorbed by roots and translocated in the plant. The available data do not adequately elucidate the nature of the residue in plants following soil application of dichlobenil. Additional data are required.

c. Radiolabeled studies on the metabolism and movement of dichlobenil in rats, rabbits, and cows have identified several metabolites that can occur in animal systems. Several dichlobenil metabolites have been identified in rat and rabbit urine and feces. If residue or animal and plant metabolism studies indicate detectable levels of BAM or other metabolites of concern, then livestock feeding studies using dichlobenil plus BAM may be required.

d. Analytical methodology for determining the levels of residues of dichlobenil and its metabolites (2,6-DCBA and BAM) in plants and animals. An adequate gas chromatographic (electron capture) method is available for tolerance enforcement and collection of data pertaining to residues of dichlobenil and 2,6-DCBA in or on plant commodities, fish, and potable water. The method used to collect BAM data must be fully described and validated.

Additonal data are required on dichlobenil, 2,6-DCBA and BAM. If the requested data reveals additional metabolites of toxicological concern other than BAM, additional analytical methods for data collection and enforcement may be required.

e. Storage stability data demonstrating residues of dichlobenil. No storage stability data were submitted to ascertain whether residues of dichlobenil are stable in or on plant commodities when stored. Therefore, none of the available data on the magnitude of residues in plants are considered adequate to support existing tolerances. If the requested metabolism data indicate the presence of additonal residues of toxicological concern in plant or animal commodities, data depicting the stability of such residues in storage will be required.

f. Data on the magnitude and levels of residues of dichlobenil and its metabolites (2,6-DCBA and BAM) in individual Raw Agricultural Commodities (RACs), animal products, and processed food and feed items. Conclusions cannot be reached regarding the magnitude of residues of dichlobenil in animal products, because the magnitude of the residue in feed items, metabolism in plants, and metabolism in animals are not adequately defined. Additional data are required.

2. Toxicology Data.

The toxicology data considered in support of the tolerances include a core-minimum subchronic oral toxicity study in rats with a NOEL of 100 ppm (50 mg/kg/day), a chronic feeding study in dogs with a NOEL of 50 ppm (1.25 mg/ kg/day), a rat teratology study with a maternal toxic NOEL of 20 mg/kg/day and a developmental NOEL of 60 mg/kg/day, and several mutagenicity studies (all negative). Refer to the toxicology section (section III B) for detailed information on available data and additional requirements.

Due to toxicity data gaps a Provisional Acceptable Daily Intake (PADI) rather than an Allowable Daily Intake (ADI) was established. The PADI is based on the 2-year dog feeding study NOEL of 50 ppm (1.25 mg/kg/day). Utilizing a safety factor of 1000 because of the data gaps, the PADI is 0.00125 mg/kg/day. This is eqivalent to a Maximum Permissible Intake (MPI) of 0.0750 mg/day for a 60 kg individual. The Theoretical Maximal Residue Contribution (TMRC) is 0.0195 mg/day based on a daily food intake of 1.5 kg (0.000325 mg/kg/day), which utilizes 26 percent of the PADI.

When data gaps have been satisfied, an ADI will be determined using the most sensitive study and the appropriate safety factor. The data gaps existing for an ADI are chronic/oncogenicity study, teratolgy study, and reproduction study.

3. Tolerances Issued.

Tolerances are established for dichlobenil and its metabolite 2,6-DCBA in or on the raw agricultural commodities: Almond hulls, apples, avocados, blackberries, blueberries, citrus, cranberries, figs, grapes, mangoes, nuts, pears, raspberries, and stone fruits.

Canadian tolerances have been established for residues of dichlobenil in or on apples, peaches, blackberries, cranberries, grapes, blueberries, and raspberries.

No Mexican tolerances or Codex Maximum Residue Limits (MRLs) have been established for dichlobenil.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

1. No referral to Special Review is being made at this time.

Rationale: None of the risk criteria listed in 40 CFR 154.7 have been met for dichlobenil. Therefore, no referral to Special Review is being made at this time.

2. The Agency will not classify dichlobenil as a restricted use pesticide.

Rationale: Present aquatic label directions permit treating a third of the weed area only. When a third of the weed area is treated, the maximum estimated residue (0.25 ppm) is below the restricted use trigger.

3. The Agency will assess the potential of ground water contamination after environmental fate data are received.

Rationale: Available data indicate there is a concern about dichlobenil's potential for persistence in soil and ground water contamination. These concerns cannot be adequately addressed until sufficient data on the technical are received.

4. The Agency is not requesting additional reentry data.

Rationale: Dichlobenil does not meet the toxicity criteria of 40 CFR 158.140 in that: 1) the acute dermal toxicity of the technical grade of active ingredient is greater than 200 mg/kg (body weight); 2) the acute oral toxicity of the technical grade of active ingredient is greater than 50 mg/kg (body weight); and 3) no other adverse effects have been evidenced.

5. The Agency will not at this time, require labeling to protect endangered species.

Rationale: Labeling is being deferred until clusters for endangered species (plant and animal) on aquatic and terrestrial noncrop sites have been developed. Until receipt of this information no labeling will be required. (See Other Science Findings, Section III C).

6. The Agency will not approve any significant *new food uses of dichlobenil until additional residue chemistry data are available to assess existing uses.

Rationale: It is Agency policy not to establish significant new uses where major data gaps exist. When additional data are evaluated, the Agency will determine whether significant new food use may be established.

7. The Agency has decided to add the metabolite BAM to the tolerance expression which already includes dichlobenil and the metabolite 2,6-DCBA.

Rationale: BAM is a potentially significant residue in plant and animal products and BAM has been implicated in adverse toxicological effects not attributable to dichlobenil *per se*. The contribution of BAM to the total residue will be determined upon receipt of the requested field studies.

8. The Agency is requiring residue data to establish tolerances for forage and hay of alfalfa and clover.

Rationale: Review of these uses indicates that the present non-food use classification for these commodities is inappropriate. Forage and hay may be diverted for livestock feed prior to or after seed harvest. Therefore, tolerances should be proposed and supporting data submitted.

9. The Agency is requiring data reflecting residues of the metabolite BAM on citrus, apples, stone fruits, cranberries, grapes, raspberries, nuts, almond hulls, avocados, figs and mangoes.

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*Significant new use is defined in 44 FR 27934, May 11, 1979. In the case of a new food or feed use, the Agency will consider as significant an increase in Theoretical Maximum Residue Contribution of greater than 1 percent.

Rationale: BAM is a major microbial metabolite of dichlobenil and is very stable in soil. This metabolite is readily absorbed and translocated by plants. Because BAM has tentatively been implicated in adverse toxicological effects not attributable to dichlobenil *per se*, we are requiring additional residue data depicting residues of BAM.

10. The Agency is requiring that the registrant make appropriate label amendments to permit use on avocados and figs or the established tolerances for residues in or on avocados and figs will be revoked.

Rationale: The available data are insufficient to assess the adequacy of the established tolerances for the combined residues of dichlobenil and its metabolite 2,6-DCBA in or on avocados and figs, because no registered uses exist. It is required that the registrant propose use directions and submit appropriate supporting data reflecting residues of dichlobenil, 2,6-DCBA, BAM and other residues of concern. Alternatively, the tolerance for residues in or on avocados and figs should be deleted from the 40 CFR.

11. The Agency is adopting the following positions regarding dichlobenil, 2,6-DCBA, and BAM residues and tolerances: (a) The Agency is requiring considerable data related to dichlobenil, 2,6-DCBA, and BAM food tolerances. (b) The Agency will revoke within one year of issuance of this Standard, the avocado and fig tolerances if no uses for a pesticide product on avocados and figs are proposed. (c) The Agency will delete the non-food classification of seed crops after the registrant submits tolerance proposals and supporting data demonstrating no residue levels in forage and hay of seed crops.

Rationale: Support for these positions are as follows: (a) The Agency lacks sufficient data to fully reassess dichlobenil tolerances. (b) The Agency seeks to avoid confusion in the user community that may arise from maintaining a crop tolerance for which there are no registered products. (c) The nature of the residue in animals is not adequately understood. On receipt of the data requested, the need for and nature of tolerances for residues in animal products will be determined. This requested residue data may increase the livestock dietary exposure concentrations.

12. The Agency is requiring that the negligible residue designation be deleted from the 40 CFR 180.231 tolerance entries.

Rationale: Under current Agency policy, negligible residues which were used to describe levels below or at the limits of detection are no longer established.

13. The Agency is requiring that the registrant(s) analyze their products for nitrosamines.

Rationale: There is a potential for formation of these contaminants during the manufacturing process and/or storage of their products.

14. The Agency is requiring that the registrant(s) submit data describing the manufacturing process, with particular emphasis on data relating to the formation of dibenzo-p-dioxins and dibenzofurans contaminants in their products.

Rationale: The potential exists for dibenzo-p-dioxin and dibenzofuran contamination of dichlobenil products based on chemical structure. We are requiring that the manufacturing process be described in a detailed enough manner to allow a determination of the likelihood of formation of these contaminants.

15. The Agency has identified certain data that will receive immediate review when submitted.

Rationale: Certain data are essential to the Agency's assessment of this pesticide and its uses and/or may trigger the need for further studies which should be initiated as soon as possible. The following studies have been identified to recieve priority review as soon as they are received by the Agency:

§158.120 Product Chemistry

61-1	Preliminary analysis
61-2	Description of beginning materials and manufacturing process
61-3	Discussion of formation of impurities (dioxin and nitrosamine data)

§158.125 Residue Chemistry

171-4	Plant metabolism
171-4	Animal metabolism
171-4	Methodology
171-4	Storage stability
171-4	Magnitude of the residue (BAM data)

§158.130 Environmental Fate

161-1	Hydrolysis
161-2	Photodegradation in water
161-3	Photodegradation in soil

162-1	Aerobic soil metabolism
162-2	Anaerobic soil metabolism
162-3	Anaerobic aquatic metabolism
164-1	Field soil dissipation
164-2	Field dissipation studies for aquatic uses
164-3	Field dissipation (forestry)

§158.135 Toxicology

81-3	Acute inhalation toxicity - rat
81-4	Primary eye irritation
81-5	Primary dermal sensitization
81-6	Dermal sensitization
83-2	Oncogenicity - rat and mouse
85-1	General metabolism

§158.145 Ecological Effects

72-2	Acute EC_{50} freshwater invertebrates
72-4	Fish early life stage and aquatic invertebrate life cycle

16. While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing dichlobenil as the sole active ingredient may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data as specified in the Data Appendices in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)).

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain dichlobenil as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, MPs must contain dichlobenil as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the ai and each inert ingredient which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and MPs containing dichlobenil provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, technical grade or MPs containing dichlobenil may be labeled for formulation into EPs registered only for the uses listed in Appendix III, EPA Index to Pesticide Chemicals--Dichlobenil. This Index lists all registered uses as well as approved maximum application rates and frequencies.

D. REQUIRED LABELING

All products must bear appropriate labeling as specified in 40 CFR 162.10. Appendix II contains information on label requirements.

No pesticide product containing dichlobenil may be released for shipment by the registrant after April, 1988 unless the product bears an amended label which complies with the requirements of this Standard.

No pesticide product containing dichlobenil may be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having so received) delivered or offered to be delivered by any person after April, 1989 unless the product bears an amended label which complies with the requirements of this Standard.

In addition to the above, the following information must appear on the labeling:

1. Ingredients Statement

The ingredient statement for MPs must list the active ingredient as:

2,6-dichlorobenzonitrile

2. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

3. Precautionary Statements

Statements for Manufacturing-Use Products

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Statements for End-Use Products

End-Use Products with Aquatic Weed Control (Nonfood) Use

Do not contaminate untreated water by cleaning of equipment or disposal of wastes. Treatment of weed areas can result in oxygen loss from decomposition of dead weeds. This loss can cause fish suffocation. Therefore, treat only 1/3 of the weed areas at a time and wait 14 days between treatments. Consult your State Environmental Regulatory Agency concerning the need for a permit before applying this product to public waters.

End-Use Products with Aquatic Food (Cranberry) Uses

Do not contaminate water by cleaning of equipment or disposal of wastes.

End-Use Products with Nonaquatic Uses (non-granular products)

Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes.

End-Use Products with Nonaquatic Uses (granular products)

Cover, collect, or incorporate granules spilled on the soil surface. Do not apply directly to water or wetlands (swamps, bogs, marshes and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes.

Worker Safety Rules

IMPORTANT! Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting. [For nongranular formulations: Before removing gloves, wash them with soap and water].

Keep all unprotected persons, children, livestock, and pets away from treated area or where there is a danger of drift.

Do not rub eyes or mouth with hands. If you feel sick in any way, STOP work and get help right away. See Statement of Practical Treatment.

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products. The Agency has decided that, in most cases, it will not require the submission of product-specific data for end use products at this time. Therefore most Registration Standards do not contain a Table C.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients. (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission. The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the Dichlobenil Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from (or are not specified in) either EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing and await EPA approval, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

F. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made before the deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. Time extensions may be considered when joint data development is planned, or when the Agency must approve a new or modified protocol before the study can be begun.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

G. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section IV.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options IV.D.1. (submit data) or IV.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing Dichlobenil as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing Dichlobenil in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing Dichlobenil as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing Dichlobenil either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Robert J. Taylor, PM
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

TGUIDE-1

GUIDE TO TABLES

Tables A and B contain listings of data requirements for the pesticide covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL 99.5% and 96% TECHNICALS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy this Requirement? (Yes, No, Partially)	Bibliographic Citation[2]/	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.120 Product Chemistry					
61-1 - Product Identity and Disclosure of Ingredients	TGAI	No		Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No		Yes[3]/	6 Months
61-3 - Discussion of Formation of Impurities	TGAI	No		Yes[4]/	6 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	TGAI	No		Yes[5]/	12 Months
62-2 - Certification of Ingredient Limits	TGAI	No		Yes[6]/	12 Months
62-3 - Analytical Methods to Verify Certified Limits	TGAI	No		Yes[7]/	12 Months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	No		Yes	6 Months
63-3 - Physical State	TGAI	No		Yes	6 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL 99.5% and 96% TECHNICALS

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation[2]/	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.120 Product Chemistry (cont'd)					
Physical and Chemical Characteristics					
63-4 - Odor	TGAI	No		Yes	6 Months
63-5 - Melting Point	TGAI	No		Yes	6 Months
63-6 - Boiling Point	TGAI	N/A[8]/		No	
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No		Yes	6 Months
63-8 - Solubility	TGAI or PAI	No		Yes[9]/	6 Months
63-9 - Vapor Pressure	PAI	No		Yes	6 Months
63-10 - Dissociation Constant	PAI	No		Yes	6 Months
63-11 - Octanol/Water Partition Coefficient	PAI	No		Yes	6 Months
63-12 - pH	TGAI	No		Yes	6 Months
63-13 -Stability	TGAI	No		Yes[10]/	6 Months
Other Requirements:					
64-1 - Submittal of Samples	TGAI	No		Yes	6 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL 99.5% and 96% TECHNICALS

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§158.120 Product Chemistry Footnotes

1/ Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).

2/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

3/ The following additional data are required for each product:

- o Details of the manufacturing process, including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process, and purification procedures and quality control measures.
- o The name and address of the manufacturer, producer, or supplier of each beginning material used to manufacture the product. Also, a copy of all available technical specifications, data sheets and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties must be submitted.
- o Registrants must analyze their products for formation of nitrosamines, and sufficient detail must be provided on the manufacturing process to determine the likelihood of formation of dibenozo-p-dioxin and dibenzofuran contamination.

4/ The following information is required:

- o A discussion of each impurity believed to be present at $\geq$ 0.1% based on knowledge of the beginning materials, all possible chemical reactions, and any contamination.

5/ In order to satisfy this data requirement, five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required, using valid analytical methods.

6/ Since certified limits were not provided, the following information is required:

- o Upper and lower limits must be provided, validated, and certified for dichlobenil in each product.
- o Upper limits must be provided, validated, and certified for each impurity present at $\geq$ 0.1% (w/w), and for each "toxicologically significant" impurity present at < 0.1% (w/w) in each product listed.
- o All nitrosamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after production, 3 months after production and 6 months after production, respectively. A method sensitive 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for each nitrosamine found.
- o Certifications should be submitted on EPA Form 8570 (Rev. 2-85).

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL 99.5% AND 96% TECHNICALS

§158.120 Product Chemistry Footnotes (cont'd)

7/ The following additional information is required:
- Quantitative methods to determine all impurities for which certified limits are required in each product.
- Each method must be accompanied by validation studies of the precision and accuracy of the method.

8/ Not applicable since the product is a solid at room temperature.

9/ Determinations must be made at 20 or 25 °C, and must be reported in ppm or g/100 ml solvent.

10/ Information regarding the effects of metal, metal ions, and elevated temperatures is required.

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
§158.125 Residue Chemistry					
171-2 - Chemical Identity[2]/		No		Yes	6 Months
171-3 - Directions for Use[3]/		Yes	product labels	No	
171-4 - Nature of Residue (Metabolism)					
- Plants	PAIRA	Partially	00113758 00137791	Yes[4]/	18 Months
- Livestock	PAIRA & Plant Metabolites	Partially	00067651 00111219 00113741 00147021	Yes[5]/	18 Mon
171-4 - Residue Analytical Method					
- Plant Residues	PAI & Metabolites	Partially	00036252 00036253 00036254 00036255 00109109 00147021 00113757 00113759 00113767 00113768 00113774 00113739 00113720 00113721 00113738 GS0147-001 GS0147-002	Yes[6]/	15 Months
- Animal Residues	PAI & Metabolites	Partially	00042489 00042490 00042491 00067652 00042488	Reserved[7]/	15 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.125 Residue Chemistry (cont'd)					
171-4 - Storage stability	PAI	No		Yes 8/	15 Months
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use9/					
- Citrus Fruits Group(RAC)	TEP	Partially	00113757 00113767	Yes10/	18 Months
Processed Food/Feed	TEP	Partially	00113757	Yes10/	24 Months
- Pome Fruits Group11/					
o Apples (RAC)	TEP	Partially	00109109 00113790	Yes12	18 Months
Processed Food/Feed	TEP	No		Yes 13/	24 Months
o Pears	TEP	Yes	00109109	No14/	18 Months
- Stone Fruits Group(RAC)	TEP	Partially	00109109 00113771 00113772 00113773	Yes15/	18 Months
Processed Food/Feed	TEP	No		Yes16/	24 Months
- Small Fruits and Berries Group17/					
o Blackberries	TEP	Partially	00113768	Yes18/	18 Months
o Blueberries	TEP	Partially	00109109	Yes19/	18 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Residue Studies for Each Food Use (cont'd)					
o Cranberries	EP	Partially	00109109 00113778 00113782 00113790 00113799	Yes[20,21]/	18 Months
o Grapes (RAC)	TEP	Partially	00113768 00113790	Yes[22],	18 Months
Processed Food/Feed	TEP	No		Yes[23]/	24 Months
o Raspberries	TEP	Partially	00113768	Yes[18]/	18 Months
- Tree Nuts Group	TEP	Partially	00113739 00113740	Yes[24]/	18 Months
o Almond Hulls	TEP	No		Yes[25]/	18 Months
- Miscellaneous Commodities	TEP				
o Avocados	TEP	Partially	00109109	Yes[26]/	18 Months
o Figs (RAC)	TEP	Partially	GS0147-001 GS0147-002	Yes[27,28]/	18 Months
Processed Food/Feed	TEP	No		Yes[28]/	24 Months
o Mangoes	TEP	Partially	00109109	Yes[29]/	18 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1/]
§158.125 Residue Chemistry (cont'd)					
171-4 - Magnitude of the Residue - Residue Studies					
- Crops Grown Solely for Seed					
o Alfalfa	EP	Partially	00036253 00036258 00113790	Yes[30/]	18 Months
o Clover	EP	Partially	00036255 00036258	Yes[31/]	18 Months
- Meat/milk/poultry/ eggs	TEP	No		Reserved[32/]	
- Potable water/fish	TEP	No		Reserved[33/]	

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

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§158.125 Residue Chemistry Footnotes

1/ Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).

2/ Refer to Product Chemistry Data Requirement Tables.

3/ See index. Except avocados and figs.

4/ Grapes and one additional orchard crop (apple, cherry, pear, or plum) are to receive soil applications of benzene-labeled [^{14}C]dichlobenil at or above 6 lb ai/A 30 days prior to harvest, under conditions comparable to those specified in the label. Exaggerated application rates may be necessary. Analyses should include hydrolysis and reextraction steps to determine conjugated ^{14}C-residues of dichlobenil. Samples from requested metabolism studies must also be analyzed using accepted enforcement methods.

5/ Ruminants and poultry must be dosed for at least 3 days with benzene-labeled [^{14}C]dichlobenil at concentrations in the total diet that will result in sufficient residues in tissues, milk, and eggs for characterization. Animals must be sacrificed within 24 hours of the final dosing. Milk and eggs must be collected twice daily. ^{14}C-Residues in muscle, fat, kidney, liver, milk, and eggs must be characterized. Samples from requested metabolism studies must also be analyzed using accepted enforcement methods. If these studies do not reveal the presence of metabolites obviously passing through BAM as an intermediate, then separate studies involving the feeding of [^{14}C]BAM may be required.

6/ Complete description of the analytical methodology, including validation data, for the detection and quantitation of BAM in oranges, apples, peaches, blackberries, blueberries, cranberries, grapes, almonds, and alfalfa. If the requested data regarding the nature of the residue in plants and animals reveal additional metabolites of toxicological concern other than BAM, additional analytical methods for data collection and enforcement may be required. Residues of the metabolites 2,6-DCBA and BAM in or on crop samples must be subjected to analysis by multiresidue protocols I, II, III, and IV available from National Technical Information Service (NTIS) under Order No. PB 86 203734/AS. If the requested data regarding the nature of the residue in plants reveal additional metabolites of toxicological concern, additional analytical methods for data collection and enforcement may be required.

7/ Data are not required at the present time because there are no tolerances for residues of dichlobenil in animal commodities. The need for such tolerances will be evaluated on receipt of data required under Nature of the Residue in Livestock (refer to footnote 5/).

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§158.125 Residue Chemistry Footnotes (cont'd)

8/ Details of storage intervals and conditions of samples used to support all established tolerances for residues of dichlobenil must be submitted. These data must be accompanied by data depicting the percent decline in residues at the time and under the conditions specified. It should be noted that all residue data requested in this Standard must be accompanied by data regarding storage intervals and conditions of sample storage, and data depicting the stability of dichlobenil residues of concern in appropriate sample substrates under the conditions and for the time intervals specified.

9/ BAM is a major microbial degradation product of dichlobenil and is very stable in soil. The metabolite is readily absorbed and translocated by plants. Because BAM has tentatively been implicated in adverse toxicological symptoms not attributable to dichlobenil per se (Toxicology Chapter of the Registration Standard for Dichlobenil dated August 28, 1986), we are requiring additional residue data depicting residues of BAM in or on certain representative group members. Complete description of the analytical methodology, including validation data, for the detection and quantitation of BAM in oranges, apples, peaches, blackberries, blueberries, cranberries, grapes, almonds, and alfalfa are required If the requested plant metabolism studies reveal the presence of additional metabolites of concern, then data will be required depicting residues of these metabolites in or on treated foods or feeds.

10/ Data must be submitted in support of this crop group tolerance depicting residues of BAM and any residues of concern other than dichlobenil and 2,6-DCBA in or on oranges (harvested at maturity) following a single spring application of a G formulation and the 50% WP formulation (each in separate tests) at 6 lb ai/A. The registrant must propose a PHI, and submit appropriate data in support of this proposal. Tests must be conducted in Florida and California. Dichlobenil, 2,6-DCBA, BAM, and any other residues of concern must be determined in dried citrus pulp, wet pulp, molasses, and oil processed from fruit bearing measurable weathered residues. Exaggerated rates may be necessary.

11/ If a crop group tolerance is desired, additional supporting residue data must be submitted for pears.

12/ Data must be submitted depicting residues of BAM and any residues of concern other than dichlobenil and 2,6-DCBA in or on apples (harvested at maturity) following ground application with the 50% WP and a G formulation (each in separate tests). Tests should be conducted in Washington, New York, Pennsylvania, California, and Virginia.

13/ Data must be submitted depicting residues of dichlobenil, 2,6-DCBA, BAM, and any other residues of concern in apple juice and dry pomace processed from apples bearing measurable weathered residues. If residues are found to concentrate in either product, appropriate food/feed additive tolerances must be proposed.

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

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§158.125 Residue Chemistry Footnotes (cont'd)

14/ Data required for apples will be translated to satisfy data requirements for pears.

15/ To meet the requirements for a crop group tolerance, data must be submitted depicting residues of dichlobenil, 2,6-DCBA, BAM, and other residues of concern in or on peaches (in California and South Carolina) and plums/fresh prunes (in Idaho, Michigan, and Washington) 30 days after one soil treatment with a G formulation (peach and plum) and a WP formulation (plum only) at 6 lb ai/A.

16/ Data must be submitted which depict the potential for concentration of dichlobenil, 2,6-DCBA, BAM, and other residue of concern in dried prunes processed from plums (fresh prunes) bearing measurable weathered residues. If concentration occurs, a food additive tolerance must be proposed.

17/ Should the registrant(s) seek a crop group tolerance, proposed use directions and supporting residue data must be submitted for strawberries, and additional data will be required to support the existing tolerances for dichlobenil in or on blueberries, cranberries, and grapes.

18/ Data must be submitted depicting residues of BAM in or on blackberries harvested at regular intervals following a soil application with a G and 50% WP formulation (in separate tests) at 5 lb ai/A. A decline study is necessary to ascertain the need for a PHI.

19/ Data must be submitted depicting residues of BAM in or on blueberries harvested at regular intervals following a soil application with a G and a WP formulation (in separate tests) at 6 lb ai/A. A decline study is necessary to ascertain the need for a PHI.

20/ Data must be submitted depicting dichlobenil, 2,6-DCBA, BAM, and other residues of concern in or on cranberries harvested after soil application of the 6.75% Multiple Active Ingredient (MAI) G formulation. Separate tests must be conducted reflecting a single spring application at 10 lb ai/A, and two or more applications at rates totaling 10 lb ai/A/season. Tests must be conducted in Washington and Oregon. Alternatively, the registrant may elect to cancel this use permitted under SLN's OR-830066 and WA-830045.

21/ Data must be submitted depicting residues of BAM in or on cranberries harvested after the last of two prebloom applications (separated by 3 weeks) with a G formulation at 4 lb ai/A (total). The registrant must propose a PHI and submit data accordingly. Tests must be conducted in Massachusetts and Wisconsin.

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§158.125 Residue Chemistry Footnotes (cont'd)

22/ Data must be submitted depicting residues of dichlobenil, 2,6-DCBA, BAM, and any other residues of concern in or on grapes following two soil applications (one in early to middle February, and one no later than May 1) with a G and a WP formulation (in separate tests) at 6 lb ai/A. The registrant must propose a PHI and submit data in support of the proposal. Tests must be conducted in California and New York.

23/ Data must be submitted depicting dichlobenil, 2,6-DCBA, BAM, and any other residues of concern in raisins, raisin waste, juice, and dry pomace derived from grapes bearing measurable weathered residues. If the data indicate that residues concentrate in any of these proposed commodities, appropriate food/feed additive tolerances must be proposed.

24/ To adequately support the established crop group tolerance, data must be submitted depicting residues of dichlobenil, 2,6-DCBA, BAM, and other residues of concern in or on almonds and pecans 30 days after a single soil application of a G formulation and, in separate tests, the 50% WP formulation, at 6 lb ai/A. Tests must be conducted using ground equipment. Tests on almonds must be conducted in California; those on pecans must be conducted in Georgia, and New Mexico or Oklahoma. Although additional data are also required for English walnuts and filberts, data requested for almonds and pecans will be substituted to fulfill data requirements for these crops.

25/ Data must be submitted reflecting residues of dichlobenil, 2,6-DCBA, BAM, and other residues of concern in or on almond hulls 30 days following a single soil application of the 50% WP and, in separate tests, a G formulation, at 6 lb ai/A. Tests must be conducted using ground equipment, and must be performed in California.

26/ Available data are insufficient to assess the adequacy of the established tolerance for dichlobenil and it's metabolite 2,6-DCBA in or on avocados because no registered uses have been proposed. We recommend that the registrant(s) propose use directions and submit appropriate supporting data. Tests must be conducted in California and Florida. Alternatively, the tolerance will be revoked.

27/ Available data are insufficient to assess the adequacy of the established tolerance and proposed use directions. Label directions for registered formulations do not presently include this commodity. The registrant must either amend the label to include figs, or the existing tolerance will be revoked. If the registrant elects to amend the label, use directions must be proposed and appropriate supporting data depicting residues of dichlobenil, 2,6-DCBA, BAM, and other residues of concern on or in figs must be submitted.

28/ If the registrant elects to amend the appropriate label to permit use of dichlobenil on figs, data must be submitted which depict the potential for concentration of dichlobenil, 2,6-DCBA, BAM, and other residues of concern during processing of dried figs from treated fresh figs bearing measurable weathered residues. If the data indicate that concentration of residues occurs upon drying, an appropriate food additive tolerance must be proposed.

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

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§158.125 Residue Chemistry Footnotes (cont'd)

29/ Data must be submitted depicting residues of dichlobenil, 2,6-DCBA, BAM, and any other residues of concern in or on mangoes (harvested at maturity) following a full season application schedule (including one soil application in early-to-middle February and a second application no later than May 1) using a G formulation at 6 lb ai/A. Applications must be conducted using ground equipment and tests must be conducted in Florida. A maximum seasonal use rate and number of applications should be proposed.

30/ The nonfood use classification of alfalfa grown for seed is inappropriate, and the registrant must (i) propose appropriate tolerances for residues of dichlobenil, 2,6-DCBA, BAM, and other residues of concern in or on alfalfa forage and hay following two applications of the 4% G formulation at 2 lb ai/A; and (ii) submit residue data in support of such tolerances. Tests should be conducted in the northwest region of the U.S. Residues must be determi in hay and the forage from which hay was prepared. Alternatively, the registrant may elect to cancel this use. Separate aerial and ground treatments must be represented.

31/ The nonfood classification of clover grown for seed is inappropriate, and the registrant(s) must: (i) propose appropriate tolerances for residues of dichlobenil, 2,6-DCBA, BAM, and other residues of concern in or on clover forage and hay following a single application of the 4% G formulation at 2 lb ai/A; and (ii) submit residue data in support of such tolerances. Tests must be conducted in California. Residues should be determined in hay and in the forage crop from which hay was prepared. Alternatively, the registrant may elect to cancel this use. Aerial and ground treatments must be represented.

32/ No conclusions can be reached at this time regarding the magnitude of residues of dichlobenil in animal products, because the magnitude of the residue in feed items (including water), metabolism in plants, and metabolism in animals are not adequately defined. Upon receipt of these data, the necessity for and nature of tolerances for residues in animal products will be determined.

33/ No conclusions can be reached at this time regarding the magnitude of residues of dichlobenil in potable water and fish, because the metabolism in plants and animals is not adequately defined and because a temporary fish tolerance reflecting 0.05 ppm dichlobenil residues in water is currently pending (PP#6G3351/FAP#6H5489). Upon receipt of these data, the appropriateness of the tolerance for residues in fish and an acceptable level in potable water will be evaluated.

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI		Yes	00112500	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI		Yes	00113796	No	
81-3 - Acute Inhalation Toxicity - Rat	TGAI		No		Yes.	9 Months
81-4 - Primary Eye Irritation	TGAI		No		Yes	9 Months
81-5 - Primary Dermal Irritation	TGAI		No		Yes	9 Months
81-6 - Dermal Sensitization	TGAI		No		Yes	9 Months
81-7 - Delayed Neurotoxicity - Hen	TGAI		No		No[2]/	
SUBCHRONIC TESTING:						
82-1 - 90- Day Feeding:						
- Rodent, and	TGAI		Yes	00107106	No	
- Nonrodent (Dog)	TGAI		No		No[3]/	

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission [1]
§158.135 Toxicology (continued)						
82-2 - 21-Day - Rabbit	TGAI		No		Reserved[4]	
82-3 - 90-Day Dermal - Rabbit	TGAI		No		No[5]	
82-4 - 90-Day Inhalation - Rat	TGAI		No		No[5]	
82-5 - 90-Day Neurotoxicity - Hen/Mammal	TGAI		No		No[6]	
CHRONIC TESTING:						
83-1 - Chronic Toxicity						
- Rodent, and	TGAI		No		Yes[7]	48 Months
- Nonrodent (Dog)	TGAI		Yes	00067649	No	
83-2 - Oncogenicity						
- Rat (preferred), and	TGAI		No		Yes[7]	48 Months
- Mouse (preferred)	TGAI		No		Yes	48 Months
83-3 - Teratogenicity						
- Rat	TGAI		Yes	00147437	No	
- Second Species	TGAI		No		Yes	12 Months
83-4 - Reproduction - Rat 2-generation	TGAI		No		Yes	30 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
§158.135 Toxicology (continued)						
MUTAGENICITY TESTING:						
84-2 - Gene Mutation (Ames Test)	TGAI		Yes	00153579 00153576 00153586	No	
84-2 - Structural Chromosomal Aberration	TGAI		Yes	00153577 00153578	No	
84-2 - Other Mechanisms of Mutagenicity	TGAI		Yes	00153580 00153581	No	
SPECIAL TESTING:						
85-1 - General Metabolism	PAI or PAIRA		No		Yes	24 Months

1/ Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).

2/ Dichlobenil is not an organophosphate; therefore, this study is not required.

3/ The subchronic dog study requirement is satisfied by the chronic dog study.

4/ The requirement for this study is reserved until environmental fate data gaps have been satisfied and it can be determined whether the aquatic uses result in human dermal exposure (i.e., washing and swimming in ponds, lakes, and reservoirs).

5/ This study is not required because of limited opportunity by this route of exposure.

6/ This is not required because an acute delayed neurotoxicity study (81-7) is not required.

7/ A study submitted (Accession No. 258695;MRID No. 00147438) needs to be resubmitted and reevaluated before it can be determined if it satisfies the requirement for a rat feeding/oncogenicity study (timeframe for submission is 6 months). The requirement for a new rat feeding/oncogenicity study will be reserved pending the final

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

§158.135 Toxicology footnotes

classification of this study.

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission1/
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B,C,D,G,H	No		Yes	9 Months
Photodegradation						
161-2 - In Water	TGAI or PAIRA	A,B,C,D,G	No		Yes	9 Months
161-3 - On Soil	TGAI or PAIRA	A,G	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA		No		No2/	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B,G,H	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes3/	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA	C,D,G	No		Yes	27 Months
162-4 - Aerobic Aquatic	TGAI or PAIRA	C,D	No		Yes	27 Months
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B,C,D,G,H	Partially	00151561	Yes4/	12 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.130 Environmental Fate (continued)						
163-2 - Volatility (Lab)	TEP		No		No[2]/	
163-3 - Volatility (Field)	TEP		No		No[2]/	
DISSIPATION STUDIES-FIELD:						
164-1 - Soil	TEP	A,B,H	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP	C,D	No		Yes	27 Months
164-3 - Forestry	TEP	G	No		Yes	27 Months
164-4 - Combination and Tank Mixes	TEP		No		No[2]/	--
164-5 - Soil, Long-Term	TEP	A,C	No		Reserved [5]/	50 Months
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A,C	No		Yes[6]/	39 Months
165-2 - Rotational Crops (Field)	TEP	A,C	No		Yes[7]/	50 Months
165-3 - Irrigated Crops	TEP	C,D	No		Yes[8]/	39 Months

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]
§158.130 Environmental Fate (continued)						
165-4 - In Fish	TGAI or PAIRA	A,B,C,D,G	No		Yes	12 Months
165-5 - In Aquatic Nontarget Organisms	TEP	D,G	No		Yes	12 Months

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[1] Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).

[2] Data are not required to support current registered uses or are otherwise not applicable for this Standard.

[3] An acceptable anaerobic aquatic metabolism study will satisfy this requirement.

[4] Data are required using the batch equilibrium method on four soils and an aquatic sediment. An aged leaching study (for degradation products) on one soil is also required.

[5] Data may be required depending on the results of field dissipation studies on terrestrial and aquatic food crops and aerobic soil metabolism studies.

[6] No restriction on the planting of rotational crops in treated areas is being imposed since there are no data available at this time to form the basis of a specific restrictive interval. However, after the required data are received and evaluated a label restriction may be imposed if it is needed.

[7] Data may be required if significant residues of concern are found in the confined rotational crop study.

[8] No restriction on the use of irrigation water used on dichlobenil-treated crops is being imposed since relevant data are not available at this time. After such data are received and evaluated a label restriction may be required.

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted?
§158.140 Reentry Protection					
132-1 - Foliar Dissipation	TEP	A,B	No		No 1/
132-1 - Soil Dissipation	TEP	A,B	No		No 1/
133-3 - Dermal Exposure	TEP	A,B	No		No 1/
133-4 - Inhalation Exposure	TEP	A,B	No		No 1/
§158.142 Spray Drift					
201-1 - Droplet Size Spectrum	TEP	A,B,C,D,G	No		No 2/
201-1 - Drift Field Evaluation	TEP	A,B,C,D,G	No		No 2/
§158.75 Other Exposure Data	TEP				No 2/

1/ Data are not required. Under 40 CFR 158.140, reentry data are not required for dichlobenil if the pesticide and its use patterns meet certain criteria. Those criteria include both toxicity and exposure. The "When Required" paragraphs of Subdivision K of the Pesticide Assessment Guidelines discuss the circumstances under which §158.140 requires reentry data.

2/ Data are not required to support current registered uses or are otherwise not applicable for this Standard.

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission1/
§158.145 Wildife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B,C,D,H	No		Yes	9 Months
71-2 - Avian Dietary LC_{50}						
- Upland Game Bird, and	TGAI	A,B,C,D,H	Yes	00022923	No	
- Waterfowl	TGAI	A,B,C,D,H	No		Yes	9 Months
71-3 - Wild Mammal Toxicity	TGAI	A,B,C,D,H	No		No	
71-4 - Avian Reproduction	TGAI	A,B	No		No	
71-5 - Simulated Field Testing						
- Mammals, and	TEP	A,B	No		No	
- Birds	TEP	A,B	No		No	

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]
§158.145 Wildife and Aquatic Organisms (cont'd)						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity						
- Coldwater Fish Species	TGAI	A,B,C,D,H	Yes	40094602	No	
- Warmwater Fish Species	TGAI	A,B,C,D,H	Yes	40094602	No	
- Warmwater Fish Species	TEP	C,D	No		No[2]	
- Coldwater Fish Species	TEP	C,D	No		No[2]	
- Coldwater Fish Species	Metabolite	D	Yes	40094602	No[3]	
- Warmwater Fish Species	Metabolite	D	Yes	40094602	No[3]	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B,C,D,H	No		Yes	9 Months
	TEP	C,D	No		No[2]	
72-3 - Acute Toxicity to Estuarine and Marine Organisms	TGAI	C,D	No		No[4]	

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
§158.145 Wildife and Aquatic Organisms (cont'd)						
AQUATIC ORGANISM TESTING (cont'd)						
72-4 - Fish Early Life Stage, and	TGAI	C,D	No		Yes[5]/	15 Months
- Aquatic Invertebrate Life Cycle	TGAI	C,D	No		Yes[5]/	15 Months
72-5 - Fish Life Cycle	TGAI	C,D	No		Reserved[6]/	
72-6 - Aquatic Organism Accumulation	TGAI	A,B,C,D	No		Yes[7]/	12 Months
72-7 - Simulated or Actual Field Testing Aquatic Organisms	TEP	D	Partial[8]/	113752	Reserved[9]/	

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

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§158.145 Wildife and Aquatic Organisms Footnotes

1/ Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).

2/ The inerts of the granular formulation are not likely to cause the product to be more toxic than technical.

3/ Reserved pending receipt and review of fate data such as photolysis, hydrolysis and aquatic field dissipation.

4/ Exposure levels as compared freshwater toxicity do not present a concern.

5/ Direct application to water exceeds 0.01, the fish LC_{50} of technical dichlobenil, and the aquatic invertebrate EC_{50} for a formulated product of dichlobenil. Reserved for cranberry use pending receipt of photolysis, hydrolysis and aquatic field dissipation.

6/ Reserved pending the results of the partial fish life cycle and aquatic field dissipation study.

7/ See data requirements for §158.130.

8/ Incomplete reporting of residue analysis mortality and growth data. Only the study on the 4% granular product could be used in partial fulfillment of this requirement.

9/ Reserved pending results of aquatic field dissipation studies and remaining acute and chronic aquatic toxicity studies.

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data To Satisfy Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission[1]/
§158.150 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	TEP	A,B,C,D	No		No	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
122-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,C,D	No		Yes	6 Months
122-1 - Vegetative Vigor	TGAI	A,B,C,D	No		Yes	6 Months
122-2 - Aquatic Plant Growth	TGAI	A,B,C,D	No		Yes	6 Months
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,C,D	No		Reserved[2]/	
123-1 - Vegetative Vigor	TGAI	A,B,C,D	No		Reserved[2]/	
123-2 - Aquatic Plant Growth	TGAI	A,B,C,D	No		Reserved[2]/	
TIER III						
124-1 - Terrestrial Field	TEP	A,B	No		Reserved[3]/	
124-2 - Aquatic Field	TEP	D	No		Reserved[3]/	

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

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§158.150 Plant Protection Footnotes

1/ Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).

2/ Reserved pending results of Tier II.

3/ Reserved pending results of Tier II.

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission[1]/
§158.155 Nontarget Insect						
NONTARGET INSECT TESTING - POLLINATORS:						
141-1 - Honeybee Acute Contact Toxicity	TGAI	A,B,G,H	Yes	00018842	No	
141-2 - Honeybee - Toxicity of Residues on Foliage	TEP	A,B,G,H	No		No[2]/	
141-4 - Honeybee Subacute Feeding Study					Reserved[3]/	
141-5 - Field Testing For Pollinators	TEP	A,B,G,H	No		No[2]/	
NONTARGET INSECT TESTING - AQUATIC INSECTS:						
142-1 - Acute Toxicity to Aquatic Insects					Reserved[4]/	
142-1 - Aquatic Insect Life Cycle Study					Reserved[4]/	
142-3 - Simulated or Actual Field Testing for Aquatic Insects					Reserved[4]/	

TABLE A

GENERIC DATA REQUIREMENTS FOR DICHLOBENIL

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data To Satisfy This Requirement? (Yes, No or Partially)	Bibliographic Citation	Must Additional Data be Submitted?	Timeframe for Submission
§158.155 Nontarget Insect (continued)						
NONTARGET INSECT TESTING - PREDATORS AND PARASITES					Reserved4/	
143-1 - thru 143-3 -						

1/ Data must be submitted within the indicated timeframes, which begin on th edate of the Guidance Document (see front cover for this date).

2/ As data from the acute contact study show low toxicity, no further testing is required.

3/ Reserved pending development of test methodology.

4/ Reserved pending Agency decision as to whether the data requirement should be established.

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DICHLOBENIL

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement? (Yes, No, Partially)	Bibliographic Citation[2]/	Must Additional Data be Submitted?	Time Frame for Submission[1]/
§158.120 Product Chemistry					
Product Identity:					
61-1 - Product Identity and Disclosure of Ingredients	MP	No		Yes	6 Months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No		Yes[3]/	6 Months
61-3 - Discussion of Formation of Impurities	MP	No		Yes[4]/	6 Months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis	MP	No		Yes[5]/	12 Months
62-2 - Certification of Limits	MP	No		Yes[6]/	12 Months
62-3 - Analytical Methods to Verify Certified Limit	MP	No		Yes[7]/	12 Months
Physical and Chemical Characteristics					
63-2 - Color	MP	No		Yes	6 Months
63-3 - Physical State	MP	No		Yes	6 Months
63-4 - Odor	MP	No		Yes	6 Months

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DICHLOBENIL

Data Requirement	Test Substance	Does EPA Have Data To Satisfy This Requirement? (Yes, No, Partially	Bibliographic Citation[2]/	Must Additional Data be Submitted?	Time Frame for Submission[1]
§158.120 Product Chemistry (Continued)					
Physical and Chemical Characteristics (Continued)					
63-7 - Density, Bulk Density, or Specific Gravity	MP	No		Yes	6 Months
63-12 - pH	MP	No		Yes	6 Months
63-14 - Oxidizing or Reducing Action	MP	No		Yes	6 Months
63-15 - Flammability	MP	No		Yes	6 Months
63-16 - Explodability	MP	No		Yes	6 Months
63-17 - Storage Stability	MP	No		Yes	15 Months
63-18 - Viscosity	MP	No		Yes	6 Months
63-19 - Miscibility	MP	No		Yes	6 Months
63-20 - Corrosion Characteristics	MP	No		Yes	6 Months
Other Requirements:					
64- 1 - Submittal of samples	MP	No		Yes	6 Months

TABLE B
PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING DICHLOBENIL

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§158.120 Product Chemistry Footnotes

1/ Data must be submitted within the indicated timeframes, which begin on the date of the Guidance Document (see front cover for this date).

2/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each manufacturing-use product. New requirements have been introduced and previously submitted data must be updated. Therefore bibliographic citations for the old data are not applicable.

3/ The following additional data are required for each product:
- o Details of the manufacturing process, including the relative amounts of beginning materials, a description of the equipment used to produce the product, reaction conditions, the duration of each step of the process, and purification procedures and quality control measures.
- o The name and address of the manufacturer, producer, or supplier of each beginning material used to manufacture the product. Also, a copy of all available technical specifications, data sheets and other documents in which the manufacturer, producer, or supplier of the beginning material describes its composition and properties must be submitted.
- ° Registrants must analyze their products for formation of nitrosamines and sufficient detail must be provided on the manufacturing process to determine the likelihood of formation of dibenzo-p-dioxin and dibenzofuran contamination.

4/ The following information is required:
- o A discussion of each impurity believed to be present at $\geq$ 0.1% based on knowledge of the beginning materials, all possible chemical reactions, and any contamination.

5/ In order to satisfy this data requirement, five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required, using valid analytical methods.

6/ Since certified limits were not provided, the following information is required:
- o Upper and lower limits must be provided, validated, and certified for dichlobenil in each product.
- o Upper and lower limits must be provided, validated, and certified for each intentionally added inert.
- o Upper limits must be provided, validated, and certified for each impurity present at $\geq$ 0.1% (w/w), and for each "toxicologically significant" impurity present at $<$ 0.1% (w/w) in each product:
- ° All nitrosamines must be identified and quantified in six samples of each product; two samples of each must be analyzed shortly after product, 3 months after production and 6 months after production, respectively. A method sensitive to 1 ppm of N-nitroso contaminants must be used. An upper limit must be provided (and certified) for each nitrosamine found.
- ° Certifications should be submitted on EPA Form 8570 Rev. 2-85.

7/ The following additional information is required:
- ° Quantitative methods to determine all impurities for which certified limits are required in each product.
- ° Quantitative methods to determine all intentionally added inerts in all products.
- ° Each method must be accompanied by validation studies of the precision and accuracy of the method.

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-8

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§162.10 Labeling requirements.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label of labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to § 162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed"; and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";

(B) "Among the least toxic chemicals known"

(C) "Pollution approved"

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to § 162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68°F (20°C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable units, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishments registration number. The producing establishment registration number preceded by the phrase "EPA Est.", of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups; those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard indicators	Toxicity categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2,000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word.--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of label front panel in square inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity category	Precautionary statements by toxicity category	
	Oral, inhalation, or dermal toxicity	Skin and eye local effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust] or spray mist]. Do not get in eyes, on skin, or on clothing [Front panel statement of practical treatment required.].	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.].	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.].
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.].	Avoid contact with skin, eyes or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.].	[No precautionary statements required.].

(ii) Environmental hazards. Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flash point	Required text
(A) PRESSURIZED CONTAINERS	
Flash point at or below 20°F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
Flash point above 20°F and not over 80°F or if the flame extension is more than 18 in. long at a distance of 6 in. from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20°F	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20°F and not over 80°F	Flammable. Keep away from heat and open flame.
Above 80°F and not over 150°F	Do not use or store near heat or open flame.

(i) *Directions for Use*--(1) *General requirements*--(i) *Adequacy and clarity of directions*. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) *Placement of directions for use*. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular." and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) *Exceptions to requirement for direction for use*--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(*1*) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(*2*) Adequate information such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(*3*) The product will not come into the hands of the general public except after incorporation into finished products; and

(*4*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(*1*) The label clearly states that the product is for use only by physicians or veterinarians;

(*2*) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(*3*) The product is also a drug and regulated under the provisions of the Federal Food, Drug and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(*1*) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the headings "Directions for Use":

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment requried.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in § 162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of § 162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use." And reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in § 162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 FR 28268, July 3, 1975; 40 FR 32329, Aug. 1, 1975; 40 FR 38571, Aug. 21, 1975, as amended at 43 FR 5786, Feb. 9, 1978]

PHYS/CHEM-1

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

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DICHLOBENIL

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DICHLOBENIL*

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TYPE PESTICIDE: Herbicide

FORMULATIONS:
Tech (99.5%)
FI (85%)
G (2%, 4%, 10%)
WP (50%)
SC/L (1.73%, 1.77%, 2.1%, 3.12%)
RTU (6.75%)

GENERAL WARNINGS AND LIMITATIONS: A terrestrial and aquatic herbicide used to control broadleaf weeds, grasses, and aquatic vegetation in ornamental woody plants, nut and fruit crops, lakes, and noncrop areas. Also controls root growth in sewer joint grout gels and in sewer lines. To control perennial weeds use either soil surface treatments in late fall (November 15 to February 15) or soil incorporated treatment immediately after application in late fall or early spring before May 1. To control annual weeds apply either in the early spring or after cultivation has removed established weeds. If treatments are followed with 0.5 to 1 inch of water by overhead irrigation, use the lower dosages. Shallow incorporation is recommended in southern areas when temperatures are high. When applying granules, a uniform application can be obtained by applying half the granules over the entire area and then repeating with the remaining granules. If application is made to dry soil, lightly sprinkle with water to moisten soil to a depth of 0.25 to 0.5 inch. Do not use on sloping areas as run-off may injure desirable plants in adjacent areas. Do not use on plants any part of which is used for human or animal consumption. Do not use on extremely light soil or in greenhouses. Do not apply to transplants, cutting beds, or newly set transplants. Do not apply if air temperatures are expected to rise above 70 F (21.1 C) within the following week. Do not disturb soil in treated areas as long as the weed control program is being maintained. Do not store product with propagative materials such as seeds, bulbs, or tubers.
Agricultural Crop Tolerances (other than those listed in the text):

Avocados	0.15 (N) ppm
Figs	0.15 (N) ppm

TIME REQUIRED FOR CONTROL: Not located.

PHYTOTOXICITY TO TARGET WEEDS: Leaves may absciss and exhibit a black or brown discoloration.

PHYTOTOXICITY TO CROPS: Not located.

MODE OF ACTION: Stimulates oxygen utilization and inhibits esterification of phosphorus, resulting in reduced meristematic cell growth and inhibition of germination.

*2,6-dichlorobenzonitrile

DICHLOBENIL

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BROADLEAF WEEDS CONTROLLED:

AAGBV	Arrowleafed tearthumb	(a)
BFAKAA	Aster	(a)
BFAOAA	Beggarsticks	(a)
BFCRBA	Bristly oxtongue thistle	(d)
XABBC	Buckhorn plantain	(d)
BFAWBG	Bull thistle	
BFBWBB	Camphorweed	
BFAWBB	Canada thistle	
DABBA	Carpetweed	
ZAAAC	Chickweed	(d)
BLAGBA	Citronmelon	
BYABBA	Common bogbean	(a)
BFBUBA	Common sunflower	
BMAJAA	Cottongrass	(a)
BFBPAA	Cudweed	
AAHBE	Curly dock	
BFDHBB	Dandelion	
BGADAA	Dodder	(a)
BFBIBB	Dogfennel	
NAFAA	Eveningprimrose	
BFCHBA	Fall hawkbit	
BFCUAA	Falsedandelion	
MAEBB	Florida pusley	
DADAA	Gisekia	
BDAEAA	Goosefoot	
AAHBA	Green sorrel	
BFCXAA	Groundsel	
BFBXAA	Hawkweed	(a)
BDAEBD	Jerusalemoak goosefoot	
EAAGAC	Knotweed	(a)(d)
EAAGBP	Ladysthumb	
BDAEAB	Lambsquarter	(d)
BVAGBE	Leafy spurge	
ZAAABA	Little hairgrass	(a)
AAGBK	Marshpepper smartweed	(a)
SABBB	Maypop passionflower	
DACBA	Minerslettuce	
BFAJBN	Mugwort	
ZAAACE	Muskrat grass	(a)
BMADAA	Nutsedge	(a)(b)(c)(e)
AAGBO	Pennsylvania smartweed	(a)
BKAWAA	Pepperweed	
AAABI	Pigweed	(d)
BFCKBB	Pineappleweed	
XABAA	Plantain	(a)
BFCEBF	Prickly lettuce	(d)
AAABP	Purslane	
BFAEAA	Ragweed	(a)
FACBI	Redroot pigweed	
AAHBB	Red sorrel	
BFARBI	Russian knapweed	

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BROADLEAF WEEDS CONTROLLED (continued)

DAKBA	Russian thistle	
KAHBA	Shepherdspurse	(d)
AAAAZ	Short wiregrass	(a)
AAGAD	Smartweed	(a)
FDCAA	Sowthistle	(d)
FAOBA	Spanishneedles	
FCABB	Spotted catsear	
VAGAA	Spurge	
MAHBA	Stranglevine	
AAGBG	Swamp smartweed	(a)
AAADE	Tideland clover	(a)
LAKBC	Virginia strawberry	(a)
AAGBB	Water smartweed	(a)
AAABM	Western lilaeopsis	(a)
AAABB	Wideleafgrass	(a)
FANBA	Wild carrot	
KBKBB	Wild mustard	
KBABA	Wild radish	
MAGBE	Woolgrass bulrush	(a)
FAJAA	Wormwood	
KADBB	Yellow rocket	
PABBG	Yellow woodsorrel	

(a) in cranberry bogs.
(b) in alfalfa (seed crop) and ladino clover (seed crop).
(c) in noncrop areas.
(d) in soil application (mineral soils).
(e) in pre-paving/lining (vinyl pool liners).

GRASSES AND OTHER MONOCOTS CONTROLLED:

ACKBA	Annual bluegrass	
AADAA	Bentgrass	(a)
ACKAA	Bluegrass	
AAVBA	Bluejoint reedgrass	(a)
QATBA	Coffeeweed	
ABRBA	Common velvetgrass	(a)
ABFAA	Crabgrass	(a)
OASBC	Florida betony	
ACUAA	Foxtail	
ACUBF	Green foxtail	(b)
ABSBD	Hare barley	
OAFBA	Henbit	
ABZBA	Italian ryegrass	(b)
YAEAA	Loosetrife	(a)
QBDBA	Marsh peavine	(a)
BABBD	Marsh St. Johnswort	(a)
ACNBA	Natalgrass	
ADAAA	Needlegrass	(a)
ADGBA	Oniongrass	(a)

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GRASSES AND OTHER MONOCOTS CONTROLLED (continued)

CABBBA	Orchardgrass	
CQABBA	Percatory bean	
COAFBC	Purple deadnettle	
CAACBA	Quackgrass	
CABOBB	Rattlesnakegrass	(a)
CABXBB	Rice cutgrass	(a)
CAADBB	Rough bentgrass	(a)
CLABAA	Rush	(a)
CABGBA	Seashore saltgrass	
CAATBE	Smooth brome	
CAAXAB	Stargrass	(a)
CABMBE	Tall fescue	
CACEBL	Texas panicum	
CACIBA	Timothy	
CACEBC	Witchgrass	

(a) in cranberry bogs.
(b) in alfalfa (seed crop) and ladino clover (seed crop).

WOODY PLANTS CONTROLLED:

BHABAA	Dogwood	(a)
AAAACF	Roots	(f)

(a) in cranberry bogs.
(f) in adhesives (grout gel) and sewage lines.

AQUATIC WEEDS CONTROLLED:

IGABAA	Chara
BBABBA	Coontail
CHACAA	Elodea
DJABAA	Naiads
CDABBB	Northern watermilfoil
AAAABN	Pondweed

NONFLOWERING PLANTS CONTROLLED:

EBAHBC	Brackenfern	(a)
ARABAA	Fiddleneck	
BTABBA	Field horsetail	(a)
FVABAA	Haircap moss	(a)
BTABAA	Horsetail	
FQABBB	Royal fern	(a)
EBAEBA	Sensitive fern	(a)
BTABBB	Water horsetail	(a)

(a) in cranberry bogs.

DICHLOBENIL

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP	
	(Agricultural Crops)	
3001BA	Alfalfa (seed crop)	N.F. Do not graze or use forage from treated areas. Do not use seed for food or feed purposes. General Information: Apply only to established stands.
	1.4-2.0 (4% G) 000400-00168	Use limited to the northwestern United States. Postemergence. Soil treatment. Apply by ground or by air. Make a second application 4 to 6 weeks after the first application but before irrigating, using 2 pounds active ingredient per acre without soil incorporation.
3001AA	Almond	0.15 (N) ppm (almond, almond hulls, apples, blueberries, grapes, mangos, nuts, pears, stone fruit) 30 day preharvest interval for nuts and stone fruit.
3001DA	Almond (nursery stock)	
4001AA	Apple	
4001DA	Apple (nursery stock)	
1009AA	Blueberry	
1009DA	Blueberry (nursery stock)	
5002AA	Cherry	
5002DA	Cherry (nursery stock)	
03009AA	English Walnut	
03009DA	English Walnut (nursery stock)	
03005AA	Filbert	
3005DA	Filbert (nursery stock)	
1021AA	Grape	
1021DA	Grape (nursery stock)	
6007AA	Mango	
6007DA	Mango (nursery stock)	
5003AA	Nectarine	
5003DA	Nectarine (nursery stock)	
5004AA	Peach	
5004DA	Peach (nursery stock)	
4003AA	Pear	
4003DA	Pear (nursery stock)	
3008AA	Pecan	
3008DA	Pecan (nursery stock)	
5005AA	Plum	
5005DA	Plum (nursery stock)	

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Almond cluster (continued)	
006AA 006DA	Prune Prune (nursery stock)	
	4-6 (2%, 4% G) 000769-00536 (50% WP) 037100-00001	Broadcast or directed spray. Soil treatment. Apply in early spring before weed germination or after cultivation has removed established weeds. Use the higher rate for hard-to-control weeds. Do not apply within 4 weeks after transplanting (6 months on pecan transplants).
	Almond (nursery stock)	See Almond cluster.
	Apple	See Almond cluster.
	Apple (nursery stock)	See Almond cluster.
1002AA 1006AA	Blackberry Raspberry	0.15 (N) ppm General Information: Apply only to established plantings. Do not apply during new shoot emergence.
	4-5 (2%, 4% G) 000769-00536 (50% WP) 037100-00001	Broadcast or directed spray. Soil treatment.
	Blueberry	See Almond cluster.
	Blueberry (nursery stock)	See Almond cluster.
	Cherry	See Almond cluster.
	Cherry (nursery stock)	See Almond cluster.

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
.010AA	Cranberry Bogs	0.15 (N) ppm (cranberries) General Information: Temporary reddening of cranberry plants may occur, especially with late spring applications or when applied to sandy bogs. Do not apply after cranberry plants start to bloom. Do not apply to young beds, newly sanded beds, or on bogs prior to or immediately after mowing for vines.
	4 (4% G) 000400-00168	Prebloom application. Two equal applications should be made with 3 to 6 weeks between treatments. Do not make a spring application if a treatment was made the previous fall.
	4-6 (4% G)	Postharvest application. Use the higher dosage on weedy bogs. Do not apply if a treatment was made the previous spring.
	[SLN] 3.4-6.8 (6.75% RTU)	SLN - Use limited to OR and WA. Soil treatment. Apply in March. Formulated with dalapon.
	English Walnut	See Almond cluster.
	English Walnut (nursery stock)	See Almond cluster.
	Filbert	See Almond cluster.
	Filbert (nursery stock)	See Almond cluster.
	Grape	See Almond cluster.
	Grape (nursery stock)	See Almond cluster.

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DICHLOBENIL

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
002AA 002DA 004AA 004DA 005AA 005DA 006AA 006DA 008AA 2008DA	Grapefruit Grapefruit (non-bearing) Lemon Lemon (non-bearing) Lime Lime (non-bearing) Oranges Oranges (non-bearing) Tangerine Tangerine (non-bearing)	0.15 (N) ppm (citrus fruit) Do not allow livestock to graze in treated areas. General Information: Do not apply during 6 months following possible freeze damage.
	3-6 (2%, 4% G) 000802-00536 (50% WP) 037100-00001	Broadcast or directed spray. Soil treatment. Apply in the spring before weeds emerge or after removing established weeds. Incorporate immediately into the soil to a depth of 1 to 2 inches using a power driven rotary hoe.
2008AA 004AA 011AA 010AA	(Cleopatra mandarin, rough lemon, sour orange, sweet orange)	
	4-6 (4% G) (50% WP)	Broadcast or directed spray. Soil treatment. Apply the first application in the early spring after removal of banks and the second in early summer, not less than 30 days after the first.
	Grapefruit (non-bearing)	See Grapefruit cluster.
3016BA	Ladino Clover (seed crop)	N.F. Do not graze or use forage from treated areas. Do not use seed for food or feed purposes. General Information: Apply only to established stands.
	1.4-2.0 (4% G) 000400-00168	Use limited to the Pacific Coastal States. Dormant application. Soil treatment. Apply by ground or by air. Make application when adequate rainfall or supplemental irrigation is assured.
	Lemon	See Grapefruit cluster.
	Lemon (non-bearing)	See Grapefruit cluster.
	Lime	See Grapefruit cluster.
	Lime (non-bearing)	See Grapefruit cluster.

Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
Mango	See Almond cluster.
Mango (nursery stock)	See Almond cluster.
Nectarine	See Almond cluster.
Nectarine (nursery stock)	See Almond cluster.
Oranges	See Grapefruit cluster.
Oranges (non-bearing)	See Grapefruit cluster.
Peach	See Almond cluster.
Peach (nursery stock)	See Almond cluster.
Pear	See Almond cluster.
Pear (nursery stock)	See Almond cluster.
Pecan	See Almond cluster.
Pecan (nursery stock)	See Almond cluster.
Plum	See Almond cluster.
Plum (nursery stock)	See Almond cluster.
Prune	See Almond cluster.
Prune (nursery stock)	See Almond cluster.
Raspberry	See Blackberry cluster.
Tangerine	See Grapefruit cluster.
Tangerine (non-bearing)	See Grapefruit cluster.

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	TERRESTRIAL NON-FOOD CROP	
	(Ornamental Plants and Forest Trees)	
5041DA	Amur Corktree	N.F.
5021DA	Arborvitae	Do not apply for 4 weeks after transplanting.
5022DA	Ash	General Information: Do not apply to fruit stock within 3 months prior to or following grafting, budding of root stocks, or planting of new grafts. Do not use on St. Lucie fine sand or Azrell fine sand. For circular areas around shrubs or trees, apply 0.33 to 4.25 ounces of product to a diameter of 2 to 6 feet, respectively. Do not apply more than 6 pounds active ingredient per acre on azaleas, boxwoods, euonymus, forsythia, heather, holly, ivy, and lilac.
4022DA	Azalea	
4151DA	Azalea (Kurume hybrids)	
4152DA	Azalea (Mollis hybrids)	
4025DA	Barberry	
4028DA	Beauty Bush	
5028DA	Birch	
5034DA	Boxelder	
4031DA	Boxwood	
4036DA	Camellia	
4037DA	Caragana	
4208DA	Cleyera Japonica	
4035DA	Cotoneaster	
5133DA	Cottonwood	
5056DA	Crabapple (ornamental)	
4050DA	Deutzia	
5043DA	Dogwood	
5047DA	Eastern Redcedar	
5049DA	Elm	
5237DA	Ellwood False Cypress	
4052DA	English Ivy	
5351DA	English Walnut	
4053DA	Euonymus	
5352DA	Filbert (ornamental)	
5051DA	Fir	
5052DA	Flowering Almond	
4061DA	Flowering Quince	
4062DA	Forsythia	
4063DA	Gardenia	
5063DA	Goldenraintree	
5067DA	Hackberry	
4068DA	Heather	
4070DA	Holly (excluding Ilex crenata, I. rotunda, I. vomitoria)	
35070DA	Honeylocust	
34072DA	Honeysuckle	
35073DA	Juniper	
34027DA	Kinnikinnick	
4215DA	Laurel	

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Amur Corktree cluster (continued)	
4081DA	Leucothoe	
4089DA	Lilac	
5075DA	Linden	
5077DA	Locust	
5082DA	Magnolia	
5083DA	Maple	
4094DA	Mock Orange	
4100DA	Nandina	
5093DA	Oak	
4199DA	Osmanthus	
4200DA	Paxistima	
5353DA	Pecan (ornamental)	
4110DA	Photinia	
5098DA	Pine	
4113DA	Pittosporum	
5099DA	Podocarpus	
5101DA	Poplar	
4088DA	Privet	
4058DA	Pyracantha	
4118DA	Rhododendron	
4119DA	Rockrose	
4120DA	Rose	
5109DA	Russian Olive	
4130DA	Spirea	
5116DA	Spruce	
4256DA	Squawcarpet	
4137DA	Viburnum	
5128DA	Weigela	
5130DA	Yew	
	4-8 (2%, 4% G) 000400-00170 (50% WP) 037100-00001	Broadcast or directed spray. Soil treatment. Apply in the late fall or in the early spring and incorporate immediately into the soil. Use the lower dosage to control annual weeds and the higher dosage to control perennial weeds.
	(General Soil Treatment and Composting)	
0008DA	Soil Application	General Information: Do not transplant into treated soils.
	10-20 (4% G) 000400-00168	Soil treatment to control nutsedge in mineral soils. Incorporate immediately to a depth of 4 to 6 inches.

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	(Noncrop, Wide Area, and General Indoor/Outdoor Treatments)	
70000A	Noncrop Areas	
		Do not seed or transplant into treated areas for 24 months. General Information: This site includes areas around buildings, roadways, fences, window wells, bicycle paths, cemetery memorials, golf cart paths, railroad, utility, and highway rights-of-way, electrical substations, lumber yards, petroleum installations, farm fuel storage tanks, storage areas, above ground tanks and pipes.
	0.23-0.45 lb a.i./ 1,000 sq.ft (4%, 10% G) 000400-00168	Soil treatment. Apply November 1 to March 1 in most areas and until April 1 in the northern United States. Use the higher dosage for hard-to-control weeds and in dry soil areas.
670110A	Pre-paving/lining	
		General Information: This site includes roadways, parking lots, recreational areas, sidewalks, and vinyl pool liners before paving/lining.
	0.23-0.28 lb a.i./ 1,000 sq.ft (4%, 10% G) 000400-00168	Soil treatment before paving with asphalt or before placement of vinyl pool liners. Distribute granules, incorporating into the soil to a depth of 2 to 4 inches, with a rake or tiller immediately after the final grade.
	3.8-4.5 lb a.i./ 1,000 sq.ft (50% WP) 037100-00001 (3.12% SC/L) 001769-00305	Soil treatment before paving with asphalt. Mix 1 gallon of product with 1.5 to 3 gallons of water for each 1,000 square feet. Do not mix with asphalt primer or asphalt. Apply solution just prior to laying the asphalt. Seal with a suitable oil base primer after application.

DRAF

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	AQUATIC NON-FOOD	
	(Aquatic Sites)	
5031MB	Lakes, Ponds, and Reservoirs	General Information: Do not use in commercial fish or shellfish waters. Do not apply to water which will be used for crop irrigation, livestock watering, or human consumption. Do not use fish from treated waters for food or feed for 90 days after treatment.
	7-10 (4%, 10% G) 000400-00171	Soil or water surface treatment to exposed bottoms or shorelines. Apply during early spring to exposed bottoms or to the water surface. Use the lower dosage if the soil is wet at the time of application, or if water is less than 1 foot deep.
	10-15 (4%, 10% G)	Water surface treatment. Use the lower dosage if shallow water is less than 2 feet deep, and the higher dosage in deep water (over 5 to 6 feet). Apply when wave action is at a minimum.
550260A	Sewage Lines	General Information: Do not treat roots in storm sewers or other drains where waste water will not be treated or controlled. Do not use in storm drains. Start treatment at the first manhole in the upstream section of the line and plug the downstream end while treating.
	— (2.1% SC/L) 001769-00255	Solution treatment. Use a solution of 300 gallons of water and 1.5 gallons of product to treat a 200-foot, 6-inch sewer line. Allow 30 to 60 minutes of treatment per section.
	[MAI] — (1.73%, 1.77% SC/L)	Foam treatment. Use 700 gallons of foam solution to fill a 400-foot, 6-inch sewer line. To obtain this rate, mix 1.75 gallons of product with 35 gallons of water. Formulated with vapam.

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	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	FORESTRY	
	(Ornamental Plants and Forest Trees)	
0019DA	Arborvitae (forest/shelterbelt)	N.F.
0020DA	Ash (forest/shelterbelt)	
0023DA	Birch (forest)	
0029DA	Boxelder (forest/shelterbelt)	
30037DA	Cottonwood (forest/shelterbelt)	
30041DA	Eastern Redcedar (forest/shelterbelt)	
0042DA	Elm (forest/shelterbelt)	
30114DA	English Walnut (forest/shelterbelt)	
30043DA	Fir (forest/shelterbelt)	
30115DA	Holly (shelterbelt)	
30048DA	Honeylocust (forest/shelterbelt)	
30050DA	Juniper (forest/shelterbelt)	
30116DA	Lilac (shelterbelt)	
30052DA	Linden (forest/shelterbelt)	
30053DA	Locust (forest/shelterbelt)	
30054DA	Magnolia (forest)	
30055DA	Maple (forest)	
30117DA	Mountainash (forest/shelterbelt)	
30057DA	Oak (forest/shelterbelt)	
30058DA	Pecan (forest/shelterbelt)	
30059DA	Pine (forest/shelterbelt)	
30060DA	Poplar (forest/shelterbelt)	
30118DA	Privet (shelterbelt)	
30119DA	Rose (shelterbelt)	
30121DA	Russian Olive (shelterbelt)	
30064DA	Spruce (forest)	

	Site, Dosage and Formulation (lb a.i./A)	Tolerance, Use, Limitations
	Arborvitae (forest/shelterbelt) cluster (continued)	
120DA	Squawcarpet (shelterbelt)	
073DA	Yew (forest/shelterbelt)	
		Refer to TERRESTRIAL NON-FOOD CROP, (Agricultural Crops), Amur Corktree cluster for pest, dose, and use information.
	INDOOR	
	(Commercial and Industrial Uses)	
0010A	Adhesives	
	100-200 ppm (50% WP) 037100-00001	For root control in grouts of sewer joints. Premanufacture incorporation. Incorporate product into the mixture of acrylamide nonomers used to produce the grout gel.
	AERIAL AND TANK MIX APPLICATIONS	
1500 AAAA	Aerial Application	
	--	Refer to TERRESTRIAL FOOD CROP (Agricultural Crops) Alfalfa (seed crop), Ladino Clover (seed crop)

EPA Index to Pesticide Chemicals

DICHLOBENIL

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Listing of Registered Pesticide Products by Formulation

9.5001 99.5% technical chemical
dichlobenil (027401)
000400-00172 000400-00175 002217-00680 037100-00004

5.0002 85% formulation intermediate
dichlobenil (027401)
000400-00176 002217-00677 037100-00005

2.0004 2% granular
dichlobenil (027401)
000400-00170 000769-00536 000802-00536 002217-00678
005584-00023 007401-00395 037100-00003 042057-00086

4.0004 4% granular
dichlobenil (027401)
000400-00168 000400-00171 000400-00177 000769-00535
002217-00675 002217-00682 037100-00002 044215-00056

10.0004 10% granular
dichlobenil (027401)
000400-00178 002217-00679 037100-00006

50.0006 50% wettable powder
dichlobenil (027401)
000400-00169 002217-00676 037100-00001 047901-00001

01.7315 1.73% soluble concentrate/liquid
dichlobenil (027401) plus sodium methyldithiocarbamate (039003)
009993-00002

01.7715 1.77% soluble concentrate/liquid
dichlobenil (027401) plus sodium methyldithiocarbamate (039003)
009993-00003

02.1015 2.1% soluble concentrate/liquid
dichlobenil (027401)
001769-00255

03.1215 3.12% soluble concentrate/liquid
dichlobenil (027401)
001769-00305

99999 State Label Registrations

AZ Reg. No.
010583-09396

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Listing of Registered Pesticide Products by Formulation (continued)

CA Reg. No.
011364-09868

NM Reg. No.
010583-03257

NY Reg. No.
038655-10448

TX Reg. No.
010583-08649

0000 Special Local Need Registrations (24(c))

6.75% liquid-ready to use
OR830066 WA830045

EPA Index to Pesticide Chemicals

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DICHLOBENIL

Appendix A-1

Listing of Active Ingredient(s) Found in Combination With the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
028901	dalapon (ANSI)	2,2-dichloroproprionic acid
039003	vapam (ISO)	sodium methyldithiocarbamate

-- Use EPA Acceptable Common/Chemical Name

EPA Index to Pesticide Chemicals

DICHLOBENIL

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Auxiliary Documentation

Registration Number	Cancellation Date
002749-00237	02-01-84
002749-00255	02-01-84
013360-00001	12-05-84

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

OFFICE OF PESTICIDE PROGRAMS
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GS0147-001	Thompson-Hayward Chemical Co.(1969) Determination of Dichlorbenil (Casoron) and its Metabolite, 2,6-Dichlorbenzoic Acid in Crops. 4 p.
GS0147-002	Donaldson, D. (1969) Dichlobenil and 2,6-Dichlorbenzoic Acid Residue analysis of Figs. 8 p.

OMB Approval No. 2000-0468

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET

EPA REGISTRATION NO.

PRODUCT NAME

APPLICANT'S NAME

DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date __________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by Citing MRID Number or EPA Accession Number	I am complying with data requirements by Submitting Data (Attached)	(For EPA Use Only) Accession Numbers Assigned
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

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Expiration Date 5/31/86

ATTACHMENT D

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________________________

Registrant's Name: ______________________________

and Address: ______________________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of generic data on the active ingredient named under FIFRA sec. 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA sec. 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula (CSF) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product,

OR

The CSF dated __________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ______________________________
and their registration number(s) is/are ______________________________

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA sec. 3(c)(2)(B).

Registrant's authorized representative: ______________________________
Signature

Dated: ____________________ ______________________________
(Typed)